UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,521	06/24/2005	Hirotaka Haro	Q94277	5337

23373 7590 11/25/2009

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
11/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/540,521	HARO, HIROTAKA	
	Examiner	Art Unit	
	Paul Zarek	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claim 5 has been cancelled by the Applicant in correspondence filed on 08/17/2009. Claims 9 and 10 are currently pending. This is the second Office Action on the merits of the claim(s) following a request for continued examination.

RESPONSE TO ARGUMENTS

2. Claims 5 and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Haro, et al. (Journal of Clinical Investigation, 2000, provided in IDS). Examiner notes that Claim 5 has been canceled by Applicant. Applicant traversed this rejection on the grounds that Haro, et al. (termed Haro #1), does not anticipate the rejected claim. Specifically, Applicant asserts that the rejected claims are drawn to a method consisting essentially of administering MMP-7 to the affected site of a herniated disc or herniated nucleus pulposus (HNP). Applicant disagrees with Examiner's contention that administration of macrophages constitutes administering a composition "consisting essentially of MMP-7." Applicant contends that Haro, et al., teach that macrophages, chondrocytes, and the interaction among them, are required for the treatment of herniated discs and HNP. Given the criticality of the macrophages in the treatment of HNP, as disclosed by Haro, et al., Applicant submits that this prior art does not teach administration of a composition consisting essentially of MMP-7. Respectfully, Examiner does not find Applicant's arguments persuasive.

3. The instant disclosure does not provide a definition of "consisting essentially of." Thus, Applicant has not disclosed the basic and novel characteristics of the invention outside of MMP-7. There is no evidence for the requirement of additional components for treating HNP or herniated discs. In the absence of such a definition, "consisting essentially of" is interpreted as "comprising." "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising.' See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355" (MPEP § 2111.03). Thus, Haro, et al., teaches administration of a composition comprising MMP-7 for the treatment of HNP. Even if Applicant had provided a definition of "consisting essentially of," Applicant's argument would not be found persuasive. Haro, et al., clearly teach the importance of MMP-7 for treating HNP: "Macrophage-derived MMP-7, but not MMP-3, was required for disc resorption and macrophage invasion of disc tissue" (pg 148, col 1, para 2, lines 1-3). However, although the MMP-7 is derived from macrophages, there is no requirement that the MMP-7 need be generated at the site of HNP; rather, all that is required is that MMP-7 be present. The presence of macrophages and chondrocytes, and the interactions among them, which Applicant asserts is required for HNP resorption, can be supplied by the host. Exogenous administration of MMP-7 would accomplish the same results as disclosed in Haro, et al. Moreover, this prior art also teaches that HNP can resolve itself spontaneously. In such instance, host macrophages provide MMP-7. Thus, the essential missing component is MMP-7, which Haro, et al., teaches to be integral to the process.

4. For the above reasons, the rejection of Claim 9 under 35 U.S.C. 102(b) as being anticipated by Haro, et al., is maintained.

5. Claim 10 was rejected under 35 U.S.C. 103(a) as being unpatentable over Haro, et al. (above). Applicant traversed this rejection on the grounds that the prior art does not teach or fairly suggest the claimed invention. Specifically, Applicant contends that Haro, et al., do not teach administering only MMP-7 along with a pharmaceutically acceptable carrier for the treatment of a herniated disc or HNP; rather, Haro, et al., disclose administering a composition comprising MMP-7 and macrophages. Applicant further asserts that MMP-7 itself is not sufficient to mediate HNP resorption, and that macrophages, chodrocytes, and the interplay between them are required to treat HNP. Applicant also contends that administration of MMP-7 alone would be inoperable, and, thus, not obvious. Finally, Applicant submits that Haro, et al., is not the closest prior art. Applicant offers Haro, et al. (Spine, 1997, already of record, termed Haro #2), and states that Applicant has demonstrated that MMP-7 was "vastly, yet unexpectedly, superior in disc resorption vis-à-vis MMP-3." Respectfully, Examiner does not find Applicant's arguments persuasive.

6. Examiner acknowledges that Haro, et al., does not administer MMP-7 alone, but that MMP-7 is administered by MMP-3 null macrophages (that is, macrophages that are incapable of producing and secreting MMP-3). However, Haro, et al., explicitly teach the importance of MMP-7 in the process of disc resorption. "Macrophage-derived MMP-7, but not MMP-3, was required for disc resorption and macrophage invasion of disc tissue" (pg 148, col 1, para 2, lines 1-3). Thus, Haro, et al., remove the requirement of additional components for treating HNP. As noted above, Haro, et al., also teach that herniated discs can be resolved spontaneously through

the infiltration of host macrophages (abstract). There is no basis to believe that administration of MMP-7 in a pharmaceutically acceptable carrier would preclude this infiltration. As such, the allegedly critical macrophage/chondrocyte interaction can be accomplished by host cells. Applicant has provided no evidence why administering MMP-7 alone for the treatment of HNP would be inoperable.

7. Applicant's contention that MMP-7 is unexpectedly superior to MMP-3 for treating herniated discs or HNP is not relevant. The instant claims do not recite an MMP-3 limitation nor was MMP-3 utilized as a reason to reject Claim 10, other than to demonstrate that it is MMP-7, rather than MMP-3 that is required for resorption (see Fig 1, with respect to MMP-3 and MMP-7 knockout mice).

8. For the above reasons, the rejection of Claim 10 under 35 U.S.C. 103(a) as being unpatentable over Haro, et al., is maintained.

Conclusion

9. Claims 9 and 10 remain rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/
Primary Examiner, Art Unit 1628